

SECTION TEN

COST AND BENEFITS OF THE FINAL PHARMACEUTICAL INDUSTRY EFFLUENT GUIDELINES AND MACT STANDARDS RULE

10.1 INTRODUCTION

10.1.1 Requirements of Executive Order 12866 and the Unfunded Mandates Reform Act (UMRA)

This section has been prepared to comply with Executive Order 12866, which requires federal agencies to assess the costs and benefits of each significant regulatory action. Although the Final Pharmaceutical Industry Effluent Guidelines by themselves are not considered a significant regulatory action, the combined effect of the effluent guidelines and the MACT standards rule could be considered to meet the definition in the executive order. The principal requirements of the Executive Order are that the Agency perform an analysis comparing the benefits of the regulation to the costs that the regulation imposes, that the Agency analyze alternative approaches to the rule, and that the need for the rule be identified. Wherever possible, the costs and benefits of the rule are to be expressed in monetary terms. To address the analytical requirements, as specified by the Executive Order, this section discusses the social costs of the rule in Section 10.2, pollutant reductions in Section 10.3, the benefits of the rule in Section 10.4, and the comparison of costs and benefits in Section 10.5. The industry has been profiled in Section Three of this EA, the technology options and regulatory alternatives were presented in Section Four, and impacts of the rule and its alternatives were discussed in Sections Five through Nine. Section 10.1.2, below, presents the need for the regulation.

This section also has been prepared to comply with Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), P.L. 104-4, which establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local and tribal governments and the private sector. Under section 202 of UMRA, EPA generally must prepare a written statement, including a cost-benefits analysis, for proposed and final rules with “federal mandates” that may result in expenditures to state, local and tribal governments, in the aggregate, or the private sectors, of \$100 million or more in any one year. Additionally, Executive Order 12875, Enhancing the Intergovernmental Partnership, aims to reduce unfunded mandates and provide

increased flexibility for states and local governments to utilize policy approaches. This executive order supplements but does not supplant Executive Order 12866.

Before promulgating an EPA rule for which a written statement is needed, section 205 of UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that might significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Although some states and local governments will incur costs to implement the Final Pharmaceutical Industry Effluent Guidelines, these costs to governments will not exceed the thresholds established by UMRA and, in general, the effluent guidelines will make it easier for POTWs to establish limits on discharge to POTWs. Although EPA does not believe the rule imposes significant or unique effects on small governments, under sections 203 and 205 of the UMRA, EPA has consulted with state and local governments.

EPA has determined that the final rule will not, by itself, contain a federal mandate that might result in expenditures of \$100 million or more for the private sector in any one year, but the combination of the final rule and the MACT rule will be greater than \$100 million in pretax 1997 dollars. Accordingly, EPA has prepared the written statement required by section 202 of the UMRA. This and previous sections of the EA constitute this statement: Sections Five and Six of the EA identify impacts to firms and facilities covered by the rule, and Sections Seven and Eight identify output, employment, and other secondary impacts of the rule.

EPA does not believe that there will be any disproportionate budgetary effects of the proposed rule on any particular areas of the country, particular types of communities, or particular industry segments. EPA's basis for this finding is the analysis of economic impacts, which is presented in the previous sections of this EA.

Furthermore, EPA has selected the "least costly, most cost-effective, and least burdensome alternative" for BPT, BCT, BAT, NSPS, PSES, and PSNS that is consistent with the CWA. This satisfies section 203 of UMRA. As part of the rulemaking, EPA has identified and considered a reasonable number of regulatory alternatives, as described in Section Four of this EA. EPA's selection from among various options is consistent with the requirements of the UMRA in terms of costs, cost-effectiveness, and burden.

10.1.2 Need for the Regulation

Executive Order 12866 requires that the Agency identify the need for the regulation being proposed. The discharge of pollutants directly or indirectly into surface water poses a threat to human health and the environment. Risks from these discharges include the potential for cancer and other adverse noncancer health effects and degradation of the environment. These discharges also might cause interference or inhibition problems at POTWs. This section discusses: (1) the reasons the marketplace does not provide for adequate pollution control absent appropriate incentives or standards; (2) the environmental factors that indicate the need for additional pollution controls for this source category; and (3) the legal requirements that dictate the necessity for and timing of this regulation.

The need for pretreatment standards for this source category arises from the failure of the marketplace to provide the optimal level of pollution control desired by society. Correction of such a market failure can require federal regulation. OMB defines market failure as the presence of externalities, natural monopolies, and inadequate information.¹ This section addresses the category of externalities, which is the category of market failure most relevant to the general case of environmental pollution.

¹ OMB, 1996. *Economic Analysis of Federal Regulation Under Executive Order 12866*, January 11.

The concept of externalities partially explains the discrepancy between the supply of pollution control provided by owners and operators of pollution sources and the level of environmental quality desired by the general population. The case of environmental pollution can be classified as a negative externality because it is an unintended byproduct of production that creates undesirable effects on human health and the environment.

In making production decisions, owners and operators will consider only those costs and benefits that accrue to them personally (i.e., internalized costs and benefits). However, the cost of environmental pollution is not borne solely by the creators of the pollution because all individuals in the polluted area (which can be quite large since pollution usually does not stay in one place) must share the social cost of exposure to the pollution. Therefore, although owners and operators might be the creators of pollution, they do not necessarily bear the full costs of the pollution. Government regulation is an attempt to internalize the costs of pollution.

If the people affected by a particular pollution source could negotiate with the party responsible for that source, the parties could negotiate among themselves to reach an economically efficient solution. The solution would be efficient because it would involve only those individuals who are affected by the pollution. In effect, the solution would involve the trading of pollution and compensation among the owner or operator and the people affected by that pollution.

Individual negotiation often does not occur in an unregulated market, however, because of high transaction costs, even if trade among the affected parties would be beneficial to all parties involved. For the majority of environmental pollution cases, the costs of identifying all the affected individuals and negotiating an agreement among those individuals is prohibitively high. Another problem preventing negotiations from taking place is that our current market system does not clearly define liability for the effects of pollution.

In the case of environmental quality, an additional problem is the public nature of this “good.” Environmental quality is a public good because it is predominantly nonexcludable and nonrival. Individuals who willingly pay for reduced pollution cannot exclude others who have not paid from also enjoying the benefits of a less polluted environment. Because many environmental amenities are nonexcludable, individuals utilize but do not assume ownership of these goods and therefore will not invest adequate resources in their protection. The result is that in the absence of government intervention, the free market will

not provide public goods, such as a clean environment, at the optimal quantity and quality desired by the general public.

In the case of the pharmaceutical industry, the result of the market's failure to promote water pollution control is that pollution of the nation's surface waters and ground waters is not controlled to the optimal level. This industry releases significant amounts of pollutants to surface waters through wastewater treatment plants. Despite state and local regulatory programs, many areas are still adversely affected by pollutant discharges by this industry. Section 10.3 discusses in detail the impacts of the regulation on reducing pollutants entering surface water.

Both UMRA and Executive Order 12866 require the statutory authority for the rule to be cited. The regulation is proposed under the authorities of sections 301, 304, 306, 307, and 501 of the Clean Water Act (the Federal Water Pollution Control Act Amendment of 1972, 33 U.S.C. 1251 et seq., as amended by the Clean Water Act of 1987, Pub. L. 100-4, also referred to as the CWA or the Act).

10.2 SOCIAL COSTS OF THE RULE

In the Development Document (as discussed in earlier sections of this EA), EPA developed costs of the Final Pharmaceutical Industry Effluent Guidelines based on the costs of labor, equipment, materials, and other resources needed for regulatory compliance. Although these costs are a major portion of the costs to society of the proposed regulation, they are not the only costs. The costs investigated earlier in this document reflect the costs from the perspective of the regulated community, not from the perspective of the whole society. In this section, EPA estimates the social cost of the regulation, including the costs to society in terms of forgone state and federal tax revenues, for the resources needed to comply with the regulation. Other cost categories, including administrative (permitting) costs and unemployment benefits administration costs are not significant, but also are estimated. EPA also adds in the social costs associated with the MACT standards rule.

10.2.1 Cost Categories

Social costs of a regulation comprise costs that go beyond just the facilities' costs of purchasing, installing, and operating pollution control equipment (compliance costs). Some of these additional costs are monetary, but many are nonmonetary. Additional monetary costs include the federal and state subsidies in the form of a tax shield, costs of administering a regulation (permitting costs), and the costs of administering unemployment benefits (unemployment benefits themselves are transfer payments, not a cost), including the cost of relocating displaced workers. Additional nonmonetary costs could include the inconvenience, discomfort, and time loss associated with unemployment, possible losses in consumer and producer surpluses, and possible slowdown in the rate of innovation if the industry bears large compliance costs. This section discusses in more detail the types of costs that may be components of a social cost estimate. Section 10.2.3 presents the estimates for the cost categories to which EPA could assign monetary values.

Compliance Costs

The largest component of social cost is the cost to industry of complying with the regulation. These costs have been discussed in Section Four, but are incomplete for the purposes of this section. The costs presented in Section Four are the posttax costs (the costs to industry after compliance costs have been expensed or depreciated for tax purposes and income taxes have been paid on earnings). These posttax costs reflect the tax shield on compliance costs. The tax shield is the cost to the state and federal governments of subsidizing, in effect, the cost of the regulation. Tax shields are also a cost to society and must be included in the estimate of social costs. EPA uses the social discount rate of 7 percent, as recommended by OMB,² as used in the economic impacts analysis (see Section Four).

Because the pretax costs include no cost passthrough assumptions, no consumer surplus is lost. Additionally, the pretax cost will incorporate the loss in producers' surplus. The pretax costs of compliance thus include losses in consumer and producer surplus.

² OMB, 1996. *Op. cit.*

These costs have not been adjusted either by baseline closures/failures of facilities or firms. The analysis in Section Six shows that all baseline failing firms own viable facilities (i.e., they do not close) postcompliance. As discussed in Section Six, EPA expects them to be sold and operated, thus they would incur compliance costs. Additionally, no nonindependent facilities (those owned by multifacility firms) are assumed to close in the baseline but are evaluated at the firm level. Since the firms can afford to operate these facilities postcompliance, EPA assumes all nonindependent facilities will install pollution control equipment.

Costs also are not adjusted downward for postcompliance closures, even though one facility is assumed to close, thus would not install or operate this equipment. The compliance cost to this facility totals \$2.7 million annually for both Final Pharmaceutical Industry Effluent Guidelines and MACT standards costs. EPA considers this cost a reasonable upper estimate of the cost to the firm of closing this facility.³ The firm will choose, to the extent possible, the less expensive of the two choices: install and operate pollution control or close the facility.

Administrative Costs

Implementing the Final Pharmaceutical Industry Effluent Guidelines will require that permitting authorities incur costs for writing, monitoring, and enforcing permits under the regulation. These costs of administering the regulation will add to the resource cost of regulatory compliance and are part of the total social cost of the regulation. Section 10.2.2.2 presents the methodology and estimates for administrative costs of the proposed rule.

Worker Dislocation Costs

EPA also investigates costs associated with worker dislocations as an additional component of social costs. These costs comprise the value to workers of avoiding unemployment and the costs of administering unemployment (the unemployment benefits themselves, as discussed above are transfer payments, not costs).

³ These liquidation costs include legal fees, broker fees, etc.

Nonmonetary Costs

Several other cost categories are not discussed in detail in the social cost estimate section. The first is loss of consumer and producer surpluses. As noted earlier, the use of the total pretax cost of compliance provides a reasonable upper limit estimate of the social cost of the regulation for pollution control including losses of consumer and producer surpluses. The cost estimate section also does not discuss the cost associated with a slowdown in the rate of innovation. Monetizing the loss associated with a slowdown in the rate of innovation is a very difficult task. Although there might be some small impact on the rate of innovation if they did not have to allocate resources to meeting the requirements of the proposed Final Pharmaceutical Industry Effluent Guidelines, a noticeable effect is relatively unlikely because compliance costs are not large relative to industry revenues, comprising at most (including costs of the MACT standards rule) only about 0.3% of those revenues on average.

10.2.2 Estimate of Social Costs

10.2.2.1 Costs of Compliance

As Table 10-1 shows, the social (pretax) cost of compliance for the selected options range from \$0 to \$36.1 million annually (\$1990), depending on option. The selected options have an annualized pretax cost of \$49.4 million (\$1990). When costs of the MACT standards rule are included (for all facilities, not just those affected by the effluent guidelines) pretax costs total \$96.8 million (\$1990).

10.2.2.2 Administrative Costs

EPA uses the methodology developed for the Metal Products and Machinery (MP&M) effluent guidelines to estimate administrative costs of this rule.⁴ From analysis of the Section 308 Survey database, EPA estimates that 286 facilities that are covered by this rule, of which 38 are direct dischargers that

⁴ U.S. EPA, 1995. *Regulatory Impact Analysis of Proposed Effluent Limitations Guidelines and Standards for the Metal Products and Machinery Industry (Phase I)*. Appendix E. Office of Water (EPA 821-R-95-023), April.

Table 10-1

**Costs of Compliance
(1990 dollars)**

Regulatory Option	Compliance Costs
BPT-A/C	\$2,016,233
BPT-B/D	\$1,121,232
BAT-A/C	\$2,926,352
BAT-B/D *	\$0
PSES-A/C	\$36,131,966
PSES-B/D	\$7,166,657
Total Selected Options	\$49,362,441
MACT wastewater emission control costs	\$8,714,027
Total MACT for effluent guidelines analysis facilities	\$40,325,058
Total MACT for effluent guidelines analysis facilities + Selected Options	\$89,687,499
Total MACT, all facilities	\$47,446,953
Total MACT + Selected Options	\$96,809,394

* BAT-B/D costs would have been \$0.3 million had this option been selected.

Source: Section 308 Survey Data and the Pharmaceutical Industry Facility and Firm Model, EPA, 1998.

currently have a permit in place. Another 248 facilities are indirect dischargers, of which only 35 reported they currently do not have a permit and only 1 provided no information. Therefore EPA expects a total of 36 facilities are subject to regulation and currently discharge to a POTW without a federally or locally mandated permit. For the purposes of the estimates here, EPA assumes that all indirect dischargers will incur incremental permitting costs because the facilities that do have permits from their local POTWs are assumed to require the same attention as those that do not. The existing permits vary widely in form and function, but are generally not of the scope mandated by the federal pretreatment standard permit system. EPA estimated the incremental administrative costs of administering the regulation for these facilities in the following five categories:

- Permit application and issuance (developing and issuing permits, providing technical guidance, conducting public hearings, and conducting evidentiary hearings);
- Inspection (conducted for initial permit development or subsequent inspection);
- Monitoring (sampling and analyzing permittee's effluent, reviewing and recording permittee's compliance self-monitoring reports, receiving, processing, and acting on a permittee's noncompliance reports, and reviewing a permittee's compliance schedule report for a permittee in compliance and a permittee not in compliance);
- Repermitting; and
- Enforcement

Although other administrative costs (e.g., identifying facilities to be permitted, providing technical guidance to permittees in years other than the first year of the permit, and repermitting a facility in significant noncompliance) might be incurred infrequently by some POTWs, EPA believes the above five categories capture the bulk of the administration burden of the proposed regulation. Note, however, that some of the administrative costs might be offset by cost savings at POTWs that need to develop local limits, since it is less time consuming for POTWs to write permits when national limits have been set. These cost savings have not been estimated.

EPA's analysis of the administrative costs of the Final Pharmaceutical Industry Effluent Guidelines is based on the estimated length of time and cost needed to perform each of the administrative functions listed above and the frequency of administrative activities for the facilities subject to regulation. The information on length of time and cost for the administrative functions was originally compiled as part of the analysis of

administrative costs for the proposed Metal Products and Machinery Industry (MP&M) Phase 1 regulation, conducted in 1995. The original sources of this data included: Information Collection Request analyses; a resource planning model used by EPA; an informal survey of six POTWs and three state permitting officials, and discussions with EPA Regional Office and headquarters permitting staff.⁵ EPA believes the time and cost of administrative functions for implementing the Final Pharmaceutical Industry Effluent Guidelines are not likely to differ materially from those for the MP&M regulation and hence the estimates developed for the MP&M regulation are used in this analysis.

Permitting activities and their associated costs and assumptions are listed in Table 10-2. The Final Pharmaceutical Industry Effluent Guidelines are concentration-based, but are incorporated into a mass-based permit limit based on average facility flow. EPA uses cost estimates for mass-based permits as a conservative estimate of the costs to prepare a permit. Generally, this approach will overstate costs.

The administrative costs assumptions specific to the Final Pharmaceutical Industry Effluent Guidelines include:

- EPA does not expect the administrative costs to increase as a result of the Final Pharmaceutical Industry Effluent Guidelines for facilities that are direct dischargers. Administrative costs for these subcategories may decrease because the technical guidance provided by EPA as a component of the rule may provide information to the permitting authorities that is likely to reduce the research required to develop permits. These cost savings have not been estimated and are not included in the administrative costs of the Final Pharmaceutical Industry Effluent Guidelines.
- EPA assumes the 241 indirect dischargers (286 total facilities minus 38 direct dischargers and 7 zero dischargers) may require some effort to permit, although the vast majority hold some type of permit. EPA uses the cost to develop a mass-based permit for a previously unpermitted facility, which should produce a somewhat high estimate of the cost to permit the indirect discharging facilities.

⁵ For more detailed information on the methodology and data sources for this analysis, see U.S. EPA, 1995. *Op. cit.* EPA adjusted the costs presented in this report from 1989 dollars to 1990 dollars by the change in the Producer Price Index (Council of Economic Advisors, 1997. *Economic Report of the President*).

Table 10-2

Administrative Cost Components and Frequency per Facility

Activity	Frequency	Percent of Facilities for Which Activity is Required	Cost Estimates (1990 dollars)		
			Low	Average	High
Develop and issue a mass-based permit at a previously unpermitted facility	1 time	100%	\$327	\$917	\$1,497
Provide technical guidance	1 time	100%	\$38	\$187	\$337
Conduct a public hearing	1 time	5%	\$1,123	\$1,576	\$1,871
Conduct an evidentiary hearing	1 time	5%	\$9,357	\$13,099	\$16,841
Permittee Inspection Flow <= 1 million gal/yr Flow > 1 million gal/yr	every 5 years annual	100%	\$52	\$475	\$898
Sample and Analyze Permittee's Effluent Flow <= 1 million gal/yr Flow > 1 million gal/yr	every 5 years annual	100%	\$304	\$727	\$1,402
Review and Data Entry of Permittee's Self-monitoring Reports Flow <= 1 million gal/yr Flow > 1 million gal/yr	every 5 years annual	100%	\$28	\$38	\$47
Receive, Process, and Act on a Permittee's Non-compliance Reports Flow <= 6.25 million gal/yr Flow > 6.25 million gal/yr	annual	10% 30%	\$112	\$131	\$150
Review a Compliance Report for a Permittee Meeting Milestones Flow <= 6.25 million gal/yr Flow > 6.25 million gal/yr	1.5 reports a year/3 years	90% 95%	\$7	\$9	\$12
Review a Compliance Schedule Report for a Permittee Not Meeting Milestones	1.5 reports a year/3 years	20%	\$112	\$150	\$187
Minor Enforcement Action, e.g., Issue an Administrative Order	annual	10%	\$299	\$599	\$898
Minor Enforcement Action, e.g., Impose an Administrative Fine	annual	5%	\$2,994	\$4,491	\$5,988
Repermit	every 5 years	100%	\$38	\$281	\$524

Sources: U.S. EPA, 1995. *Op. cit.*, and Council of Economic Advisors, 1997. *Economic Report of the President*.

The frequency and percent of facilities associated with certain permitting activities varies by the amount of process wastewater generated (see EPA, 1995, *op. cit.*, for details). Table 10-3 summarizes the facility counts by flow category.

Table 10-4 summarizes the number of facilities incurring costs by activity for a 16-year period following promulgation of the rule. The 16-year period is consistent with the period used in the cost-annualization model for the compliance costs. These costs are then annualized over the 16-year period at the 7 percent real social discount rate. EPA used the information in Tables 10-2 and 10-3 to calculate low, average, and high estimates for administrative costs of the rule. The estimated average annualized cost of \$206,585 (\$1990) is used as the social cost of administering the rule (see Table 10-5). Even with the conservative assumptions used in the analysis, administrative costs are less than 1 percent of the estimated compliance costs.

10.2.2.3 Unemployment Costs

EPA does not calculate an additional cost of unemployment based on the willingness of workers to pay to avoid unemployment (although the Agency does compute the cost of administering unemployment benefits to workers in facilities projected to close post compliance later in this section) for the following reason. It is important to recall that EPA estimates the cost of the regulation as the cost to all facilities—both those that would stay open and incur compliance costs and those that are estimated to close and not incur these costs. The social cost of worker displacement is reflected in workers' willingness to pay to avoid unemployment. If the workers' willingness to pay to avoid unemployment exceeds the pollution control cost (assuming the ability of labor and management to negotiate a solution, e.g., wage cuts for workers), then pollution control equipment would be installed and operated at the facility. If the pollution control cost exceeds the willingness (or the ability) of workers to pay to avoid facility closure, then retaining that cost in the industry-wide estimate provides an upper bound for the social cost of the proposed regulation, including the cost of worker dislocation. In other words, the social costs of worker dislocation should not be added to the estimated cost of the regulation when the costs of compliance at facilities that close due to the regulation are included in that estimate, because to do so would be double-counting. Therefore, EPA assumes that the cost of compliance at facilities that are estimated to close as a result of the proposed regulation is the upper limit estimate of workers' willingness to pay to avoid unemployment (plus any liquidation costs; see

Table 10-3

Facility Counts by Flow Subcategory

Flow Category	Number of Facilities		
	A/C Indirects	B/D Indirects	Total
Less than 1 million gallons per year	87	153	240
Greater than 1 million gallons per year	1	0	1
Total	88	153	241

Source: Section 308 Survey Data.

Table 10-4

Facility Counts by Year and Administrative Activity

Activity	Facility Counts															
	Year Relative to Rule Promulgation															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Issue a permit	241															
Provide technical guidance	241															
Conduct a public hearing	12															
Conduct an evidentiary hearing	12															
Inspect a permittee	241	1	1	1	1	241	1	1	1	1	241	1	1	1	1	241
Sample effluent	241	1	1	1	1	241	1	1	1	1	241	1	1	1	1	241
Review self-monitoring report	241	1	1	1	1	241	1	1	1	1	241	1	1	1	1	241
Process NCR	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24
Review CSR: compliance	217			217			217			217			217			217
Review CSR: non-compliance	48			48			48			48			48			48
Repermit						241					241					241
Issue an administrative order	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24
Enforcement seeking penalty	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12

Note: All facilities are assumed permitted in the first year. The compliance schedule is assumed to span three years. See Table 10-2 for assumptions.

Table 10-5

**Administrative Costs of the Regulation
(1990 dollars)**

Estimate	Annualized Administrative Cost of the Proposed Rule
Low	\$95,179
Average	\$206,585
High	\$333,295

Source: Tables 10-2, 10-3, and 10-4.

discussion above). Thus, EPA does not add a willingness to pay to avoid unemployment to the costs of worker dislocations.

On the other hand, unemployment benefits administration costs are an additional social cost that must be considered. One recent RIA has provided information on unemployment benefits administration costs, noting that they are about \$100 per laid-off worker (a one-time cost).⁶ The maximum number of worker dislocations estimated in Section Seven are those estimated based on output losses in the U.S. economy. The selected options are associated with total maximum, nationwide employment losses of 1,014 FTEs (associated with the Final Pharmaceutical Industry Effluent Guidelines only) or 1,842 FTEs (including losses associated with the MACT standards rule). Note that this estimate overstates total dislocations, since many of these losses are offset by sizable gains (see Section Seven), some which may occur within the same facility (e.g., production worker becomes pollution control equipment operator). Furthermore, these losses are really hours lost, not necessarily workers lost. These losses therefore most likely substantially overstate actual job losses. EPA, however, conservatively uses the 1,014 (without the MACT standards rule) to 1,842 FTEs (with the MACT standards rule) to mean jobs. EPA estimates that maximum unemployment benefits administration costs for the options will range from \$2,300 to \$74,200, depending on the subcategory. Over the 16-year time frame of the analysis and at a 7 percent discount rate, this cost by subcategory ranges from \$240 to \$7,860 per year, for a total of \$10, 730 annually over all selected options.

Note that a multifacility firm might consider increased unemployment insurance premiums in its decision to close a facility. Because compliance costs for facilities owned by multifacility firms are already included in the estimate of social costs, to the extent such increased premiums are used to pay for the costs of administering unemployment benefits, adding these costs to the compliance costs of facilities that close postcompliance will overstate costs.

10.2.2.4 Total Social Costs

Table 10-6 presents the total social costs associated with each of the selected options. These costs range from \$1.1 million to \$36.2 million (\$1990) annually, depending on the option. The selected options are

⁶ U.S. EPA, 1995. *Op. cit.*

Table 10-6

**Social Costs of Compliance
(thousands of 1990 dollars)**

Regulatory Option	Compliance Costs	Administrative Costs	Unemployment Benefits Administration Costs	Total Costs
BAT-A/C (with BPT)	\$4,942.59	\$0.00	\$1.07	\$4,943.66
BAT-B/D (with BPT)	\$1,121.23	\$0.00	\$0.24	\$1,121.48
PSES-A/C	\$36,131.97	\$76.02	\$7.86	\$36,215.84
PSES-B/D	\$7,166.66	\$130.57	\$1.56	\$7,298.78
Total Selected Options	\$49,362.44	\$206.59	\$10.73	\$49,579.77
Total MACT, effluent guidelines facilities	\$40,325.06	NA *	\$8.77	\$40,333.83
Total MACT, all facilities	\$47,446.95	NA *	\$10.32	\$47,457.27
Total MACT, effluent guidelines + Selected Options	\$89,687.50	\$206.59	\$19.50	\$89,913.59
Total MACT, all facilities + Selected Options	\$96,809.39	\$206.59	\$21.06	\$97,037.04

* Administrative costs were not calculated for MACT but are not expected to be small relative to the total costs of the two rules combined.

associated with annual total social costs of \$49.6 million (\$1990). When MACT standards costs are added in, annual social costs total \$97.0 million (\$1990).

10.3 POLLUTANT REDUCTIONS

Tables 10-7 through 10-10 present the results of EPA's loadings estimates by option (see EPA's Development Document for how the loadings and loadings reductions were calculated). The table presents raw loads, baseline loads, and postcompliance loads, along with load reductions in both pounds and in pounds-equivalent (PE), which are calculated on the basis of toxic weighting factors (TWFs). TWFs allow EPA to weight the pounds removed by the relative toxicity of each pollutant for which a removal is measured. EPA's *Cost-Effectiveness Analysis for Final Effluent Limitations Guidelines and Standards for the Pharmaceutical Industry* discusses in detail how PEs are calculated. The selected options are associated with postcompliance removals of 16.2 million pounds and 373,198 PEs from waters of the United States. Note that these removals do not include the air removals associated with the MACT standards rule. These removals amount to an additional 48 million pounds.⁷

10.4 ASSESSMENT OF BENEFITS

10.4.1 Introduction

This section presents an assessment of the annual, nationwide benefits of the Final Pharmaceutical Industry Effluent Guidelines, as well as the benefits expected to accrue from the corresponding MACT standards rule. This assessment considers the benefits expected to result from implementation of these rules due to reductions in effluent loadings and air emissions from four sources (wastewater for the Final Pharmaceutical Industry Effluent Guidelines and wastewater, process vents, storage tanks, and equipment leaks emission controls for the MACT standards rule). A variety of human health, environmental, and POTW benefits might result from these reductions. The benefit categories considered in this assessment of

⁷ U.S. EPA, 1998. *National Emission Standards for Hazardous Air Pollutants for Source Categories: Pharmaceuticals Production*.

Table 10-7

**Industry Loads and Removals by Pollutant
BAT-A/C Facilities**

Pollutant Code	Pollutant Name	Removals (lbs/yr)	Toxic Weighting Factor	PE Removals
CN-	Cyanide	0	1.08E+00	0
CHEM3	Acetonitrile	1,146	8.50E-05	0
CHEM9	Ammonia-N	800,913	2.70E-03	2,162
CHEM10	Amyl Acetate, n-	1,616	8.60E-04	1
CHEM11	Pentanol, 1- (amyl alcohol)	52,174	1.60E-04	8
CHEM12	Aniline	0	1.50E+00	0
CHEM15	Benzene	0	4.80E-01	0
CHEM25	Methyl ethyl ketone	0	2.90E-04	0
CHEM26	Butyl acetate, n-	0	3.10E-03	0
CHEM27	Butanol, 1- (n-butyl alcohol)	0	1.70E-03	0
CHEM29	Methyl-2-propanol, 2- (tert-butyl alcohol)	0	3.20E-05	0
CHEM35	Chlorobenzene	0	1.10E-02	0
CHEM37	Trichloromethane (chloroform)	4,080	1.00E-01	408
CHEM48	Dichlorobenzene, 1,2-	0	1.20E-02	0
CHEM51	Dichloroethane, 1,2-	147	1.50E+00	221
CHEM55	Diethylamine	0	2.80E-04	0
CHEM60	Dimethylacetamide, N,N-	0	2.09E-06	0
CHEM62	N,N-Dimethylaniline	0	8.30E-02	0
CHEM64	Dimethylformamide, N,N-	0	2.40E-06	0
CHEM66	Dimethyl sulfoxide	3,712	1.65E-06	0
CHEM67	Dioxane, 1,4-	0	1.80E-01	0
CHEM70	Ethanol	195,517	5.80E-04	113
CHEM71	Ethyl acetate	87,223	7.60E-04	66
CHEM77	Ethylene glycol	0	8.40E-05	0
CHEM79	Formaldehyde	0	2.30E-03	0
CHEM80	Formamide	0	0.00E+00	0
CHEM84	Heptane, n-	0	6.20E-02	0
CHEM87	Hexane, n-	241	3.10E-02	7
CHEM93	Methyl propanal, 2- (isobutyraldehyde)	0	2.10E-03	0
CHEM94	Isopropanol (2-propanol)	165,987	5.60E-03	930
CHEM95	Isopropyl Acetate	286	6.90E-05	0
CHEM96	Isopropyl Ether	0	6.10E-04	0
CHEM97	Methanol	712,931	3.30E-04	235
CHEM101	Methoxyethanol, 2- (methyl cellosolve)	0	1.60E-01	0
CHEM102	Dichloromethane (methylene chloride)	41,905	1.20E-01	5,029
CHEM103	Methyl formate (formic acid, methyl ester)	8,437	8.90E-06	0
CHEM105	Methyl isobutyl ketone	14,462	2.10E-03	30
CHEM113	Petroleum Naptha	0	6.70E-02	0
CHEM114	Phenol	8,995	2.83E-02	254
CHEM115	Polyethylene Glycol 600	0	5.60E-05	0
CHEM117	Propanol, 1- (n-propanol)	0	2.70E-05	0
CHEM118	Acetone	17,832	1.60E-03	29
CHEM124	Pyridine	0	1.60E-01	0
CHEM129	Tetrahydrofuran	31,821	7.00E-03	223
CHEM130	Toluene	8,042	6.40E-03	51
CHEM136	Triethylamine	0	1.50E-04	0
CHEM139	Xylenes	2,581	4.30E-03	11
CHEMBOD	Biochemical Oxygen Demand 5-day	0	0.00E+00	0
CHEMCOD	Chemical Oxygen Demand	0	0.00E+00	0
CHEMTSS	Total Suspended Solids	0	0.00E+00	0
Totals		2,160,048		9,780

Source: U.S. EPA, 1998. Cost-Effectiveness Analysis of Final Effluent Limitations Guidelines and Standards for Existing and New Sources for the Pharmaceutical Industry.

Table 10-8
Industry Loads and Removals by Pollutant
BAT-B/D Facilities

Pollutant Code	Pollutant Name	Removals (lbs/yr)	Toxic Weighting Factor	PE Removals
CN-	Cyanide	0	1.08E+00	0
CHEM3	Acetonitrile	0	8.50E-05	0
CHEM9	Ammonia-N	0	2.70E-03	0
CHEM10	Amyl Acetate, n-	0	8.60E-04	0
CHEM11	Pentanol, 1- (amyl alcohol)	0	1.60E-04	0
CHEM12	Aniline	0	1.50E+00	0
CHEM15	Benzene	0	4.80E-01	0
CHEM25	Methyl ethyl ketone	0	2.90E-04	0
CHEM26	Butyl acetate, n-	0	3.10E-03	0
CHEM27	Butanol, 1- (n-butyl alcohol)	0	1.70E-03	0
CHEM29	Methyl-2-propanol, 2- (tert-butyl alcohol)	0	3.20E-05	0
CHEM35	Chlorobenzene	0	1.10E-02	0
CHEM37	Trichloromethane (chloroform)	0	1.00E-01	0
CHEM48	Dichlorobenzene, 1,2-	0	1.20E-02	0
CHEM51	Dichloroethane, 1,2-	0	1.50E+00	0
CHEM55	Diethylamine	0	2.80E-04	0
CHEM60	Dimethylacetamide, N,N-	0	2.09E-06	0
CHEM62	N,N-Dimethylaniline	0	8.30E-02	0
CHEM64	Dimethylformamide, N,N-	0	2.40E-06	0
CHEM66	Dimethyl sulfoxide	0	1.65E-06	0
CHEM67	Dioxane, 1,4-	0	1.80E-01	0
CHEM70	Ethanol	7,477	5.80E-04	4
CHEM71	Ethyl acetate	0	7.60E-04	0
CHEM77	Ethylene glycol	0	8.40E-05	0
CHEM79	Formaldehyde	171	2.30E-03	0
CHEM80	Formamide	0	0.00E+00	0
CHEM84	Heptane, n-	0	6.20E-02	0
CHEM87	Hexane, n-	0	3.10E-02	0
CHEM93	Methyl propanal, 2- (isobutyraldehyde)	0	2.10E-03	0
CHEM94	Isopropanol (2-propanol)	14,646	5.60E-03	82
CHEM95	Isopropyl Acetate	0	6.90E-05	0
CHEM96	Isopropyl Ether	0	6.10E-04	0
CHEM97	Methanol	0	3.30E-04	0
CHEM101	Methoxyethanol, 2- (methyl cellosolve)	0	1.60E-01	0
CHEM102	Dichloromethane (methylene chloride)	0	1.20E-01	0
CHEM103	Methyl formate (formic acid, methyl ester)	0	8.90E-06	0
CHEM105	Methyl isobutyl ketone	0	2.10E-03	0
CHEM113	Petroleum Naptha	0	6.70E-02	0
CHEM114	Phenol	0	2.83E-02	0
CHEM115	Polyethylene Glycol 600	46	5.60E-05	0
CHEM117	Propanol, 1- (n-propanol)	0	2.70E-05	0
CHEM118	Acetone	0	1.60E-03	0
CHEM124	Pyridine	0	1.60E-01	0
CHEM129	Tetrahydrofuran	0	7.00E-03	0
CHEM130	Toluene	0	6.40E-03	0
CHEM136	Triethylamine	0	1.50E-04	0
CHEM139	Xylenes	0	4.30E-03	0
CHEMBOD	Biochemical Oxygen Demand 5-day	0	0.00E+00	0
CHEMCOD	Chemical Oxygen Demand	0	0.00E+00	0
CHEMTSS	Total Suspended Solids	0	0.00E+00	0
Totals		22,339		87

Source: U.S. EPA, 1998. Cost-Effectiveness Analysis of Final Effluent Limitations Guidelines and Standards for Existing and New Sources for the Pharmaceutical Industry.

Table 10-9

**Industry Loads and Removals by Pollutant
PSES-A/C Facilities**

Pollutant Code	Pollutant Name	Removals (lbs/yr)	POTW Removal Efficiency (%)	Removals After POTW (lbs/yr)	Toxic Weighting Factor	PE Removals
CN-	Cyanide	0	50%	0	1.08E+00	0
CHEM3	Acetonitrile	0	0%	0	8.50E-05	0
CHEM9	Ammonia-N	1,425,793	82%	259,494	2.70E-03	701
CHEM10	Amyl Acetate, n-	294,153	83%	50,594	8.60E-04	44
CHEM11	Pentanol, 1- (amyl alcohol)	0	83%	0	1.60E-04	0
CHEM12	Aniline	0	80%	0	1.50E+00	0
CHEM15	Benzene	120,896	19%	98,047	4.80E-01	47,063
CHEM25	Methyl ethyl ketone	0	83%	0	2.90E-04	0
CHEM26	Butyl acetate, n-	412,547	83%	70,958	3.10E-03	220
CHEM27	Butanol, 1- (n-butyl alcohol)	0	80%	0	1.70E-03	0
CHEM29	Methyl-2-propanol, 2- (tert-butyl alcohol)	0	81%	0	3.20E-05	0
CHEM35	Chlorobenzene	84,094	18%	69,042	1.10E-02	759
CHEM37	Trichloromethane (chloroform)	45,219	1%	44,812	1.00E-01	4,481
CHEM48	Dichlorobenzene, 1,2-	16,376	78%	3,553	1.20E-02	43
CHEM51	Dichloroethane, 1,2-	546	77%	124	1.50E+00	186
CHEM55	Diethylamine	61,644	67%	20,466	2.80E-04	6
CHEM60	Dimethylacetamide, N,N-	0	79%	0	2.09E-06	0
CHEM62	N,N-Dimethylaniline	0	83%	0	8.30E-02	0
CHEM64	Dimethylformamide, N,N-	0	79%	0	2.40E-06	0
CHEM66	Dimethyl sulfoxide	0	95%	0	1.65E-06	0
CHEM67	Dioxane, 1,4-	0	75%	0	1.80E-01	0
CHEM70	Ethanol	110	89%	12	5.80E-04	0
CHEM71	Ethyl acetate	1,693,800	83%	291,334	7.60E-04	221
CHEM77	Ethylene glycol	0	96%	0	8.40E-05	0
CHEM79	Formaldehyde	0	85%	0	2.30E-03	0
CHEM80	Formamide	0	67%	0	0.00E+00	0
CHEM84	Heptane, n-	17,502	37%	11,061	6.20E-02	686
CHEM87	Hexane, n-	1,133,860	37%	716,599	3.10E-02	22,215
CHEM93	Methyl propanal, 2- (isobutyraldehyde)	29,737	73%	8,088	2.10E-03	17
CHEM94	Isopropanol (2-propanol)	11	81%	2	5.60E-03	0
CHEM95	Isopropyl Acetate	9,426	83%	1,621	6.90E-05	0
CHEM96	Isopropyl Ether	9,280	83%	1,596	6.10E-04	1
CHEM97	Methanol	22	80%	4	3.30E-04	0
CHEM101	Methoxyethanol, 2- (methyl cellosolve)	978,930	15%	832,091	1.60E-01	133,135
CHEM102	Dichloromethane (methylene chloride)	677,934	15%	577,600	1.20E-01	69,312
CHEM103	Methyl formate (formic acid, methyl ester)	23,283	83%	4,005	8.90E-06	0
CHEM105	Methyl isobutyl ketone	254,906	81%	48,942	2.10E-03	103
CHEM113	Petroleum Naptha	0	80%	0	6.70E-02	0
CHEM114	Phenol	0	95%	0	2.83E-02	0
CHEM115	Polyethylene Glycol 600	0	96%	0	5.60E-05	0
CHEM117	Propanol, 1- (n-propanol)	0	88%	0	2.70E-05	0
CHEM118	Acetone	2,234,971	83%	373,240	1.60E-03	597
CHEM124	Pyridine	0	0%	0	1.60E-01	0
CHEM129	Tetrahydrofuran	91,062	83%	15,663	7.00E-03	110
CHEM130	Toluene	640,348	36%	411,104	6.40E-03	2,631
CHEM136	Triethylamine	374,837	83%	64,472	1.50E-04	10
CHEM139	Xylenes	22,140	20%	17,624	4.30E-03	76
CHEMBOD	Biochemical Oxygen Demand 5-day	0	0%	0	0.00E+00	0
CHEMCOD	Chemical Oxygen Demand	0	0%	0	0.00E+00	0
CHEMTSS	Total Suspended Solids	0	0%	0	0.00E+00	0
Totals		10,653,427		3,992,148		282,614

Source: U.S. EPA, 1998. Cost-Effectiveness Analysis of Final Effluent Limitations Guidelines and Standards for Existing and New Sources for the Pharmaceutical Industry.

Table 10-10
Industry Loads and Removals by Pollutant
PSES-B/D Facilities

Pollutant Code	Pollutant Name	Removals (lbs/yr)	POTW Removal Efficiency (%)	Removals After POTW (lbs/yr)	Toxic Weighting Factor	PE Removals
CN-	Cyanide	0	50%	0	1.08E+00	0
CHEM3	Acetonitrile	0	0%	0	8.50E-05	0
CHEM9	Ammonia-N	0	82%	0	2.70E-03	0
CHEM10	Amyl Acetate, n-	810,977	83%	139,488	8.60E-04	120
CHEM11	Pentanol, 1- (amyl alcohol)	0	83%	0	1.60E-04	0
CHEM12	Aniline	0	80%	0	1.50E+00	0
CHEM15	Benzene	0	19%	0	4.80E-01	0
CHEM25	Methyl ethyl ketone	0	83%	0	2.90E-04	0
CHEM26	Butyl acetate, n-	0	83%	0	3.10E-03	0
CHEM27	Butanol, 1- (n-butyl alcohol)	0	80%	0	1.70E-03	0
CHEM29	Methyl-2-propanol, 2- (tert-butyl alcohol)	0	81%	0	3.20E-05	0
CHEM35	Chlorobenzene	0	18%	0	1.10E-02	0
CHEM37	Trichloromethane (chloroform)	0	1%	0	1.00E-01	0
CHEM48	Dichlorobenzene, 1,2-	0	78%	0	1.20E-02	0
CHEM51	Dichloroethane, 1,2-	0	77%	0	1.50E+00	0
CHEM55	Diethylamine	0	67%	0	2.80E-04	0
CHEM60	Dimethylacetamide, N,N-	0	79%	0	2.09E-06	0
CHEM62	N,N-Dimethylaniline	0	83%	0	8.30E-02	0
CHEM64	Dimethylformamide, N,N-	0	79%	0	2.40E-06	0
CHEM66	Dimethyl sulfoxide	0	95%	0	1.65E-06	0
CHEM67	Dioxane, 1,4-	0	75%	0	1.80E-01	0
CHEM70	Ethanol	0	89%	0	5.80E-04	0
CHEM71	Ethyl acetate	11,639	83%	2,002	7.60E-04	2
CHEM77	Ethylene glycol	0	96%	0	8.40E-05	0
CHEM79	Formaldehyde	0	85%	0	2.30E-03	0
CHEM80	Formamide	0	67%	0	0.00E+00	0
CHEM84	Heptane, n-	0	37%	0	6.20E-02	0
CHEM87	Hexane, n-	0	37%	0	3.10E-02	0
CHEM93	Methyl propanal, 2- (isobutyraldehyde)	0	73%	0	2.10E-03	0
CHEM94	Isopropanol (2-propanol)	300	81%	58	5.60E-03	0
CHEM95	Isopropyl Acetate	217,733	83%	37,450	6.90E-05	3
CHEM96	Isopropyl Ether	0	83%	0	6.10E-04	0
CHEM97	Methanol	0	80%	0	3.30E-04	0
CHEM101	Methoxyethanol, 2- (methyl cellosolve)	0	15%	0	1.60E-01	0
CHEM102	Dichloromethane (methylene chloride)	785,175	15%	668,969	1.20E-01	80,276
CHEM103	Methyl formate (formic acid, methyl ester)	0	83%	0	8.90E-06	0
CHEM105	Methyl isobutyl ketone	0	81%	0	2.10E-03	0
CHEM113	Petroleum Naptha	0	80%	0	6.70E-02	0
CHEM114	Phenol	1	95%	0	2.83E-02	0
CHEM115	Polyethylene Glycol 600	0	96%	0	5.60E-05	0
CHEM117	Propanol, 1- (n-propanol)	0	88%	0	2.70E-05	0
CHEM118	Acetone	1,520,984	83%	254,004	1.60E-03	406
CHEM124	Pyridine	0	0%	0	1.60E-01	0
CHEM129	Tetrahydrofuran	0	83%	0	7.00E-03	0
CHEM130	Toluene	0	36%	0	6.40E-03	0
CHEM136	Triethylamine	0	83%	0	1.50E-04	0
CHEM139	Xylenes	0	20%	0	4.30E-03	0
CHEMBOD	Biochemical Oxygen Demand 5-day	0	0%	0	0.00E+00	0
CHEMCOD	Chemical Oxygen Demand	0	0%	0	0.00E+00	0
CHEMTSS	Total Suspended Solids	0	0%	0	0.00E+00	0
Totals		3,346,808		1,101,971		80,807

Source: U.S. EPA, 1998. Cost-Effectiveness Analysis of Final Effluent Limitations Guidelines and Standards for Existing and New Sources for the Pharmaceutical Industry.

the Final Pharmaceutical Industry Effluent Guidelines and MACT standards rule are identified below. Specifically, this assessment addresses the following:

- Human health and agricultural benefits due to reductions in emissions to air of ozone precursors (i.e., reductions in volatile organic compounds [VOC] emissions)
- Human health benefits due to reductions in excess cancer risk
- Ecological and recreational benefits (environmental) due to improved water quality, including intrinsic benefits
- Benefits from reductions in interference and passthrough problems, improvements in worker health, and reductions in analytical costs at POTWs
- Human health benefits due to reductions in systemic and other risks, such as risk of developmental effects or individual organ toxicity

For the first three benefit categories, sufficient information is available to monetize the benefits of the final rules. The dollar magnitude of the benefits for the other two benefit categories cannot be quantified. EPA selected pollutants of concern if they met the following criteria: (1) they were found in treatable concentrations at a number of facilities; (2) they had discharge loadings greater than 3,000 pounds per year; (3) they were treatable by technology; and (4) they were quantified by an existing approved analytical method. Pollutants meeting these criteria were included in the modeling performed for the environmental assessment. A fifth selection criterion was used to identify pollutants to be regulated. This criterion required that at least 1,000 pounds per year of a pollutant be estimated to be removable from receiving streams as a result of the Final Pharmaceutical Industry Effluent Guidelines. This assessment also includes estimates for those benefits that would accrue if only regulated pollutants are considered. The methodology and data used in the estimate of all benefits, as well as the limitations of the analyses, are described in detail in the *Environmental Assessment of the Final Industry Guidelines for the Pharmaceutical Manufacturing Industry* (Environmental Assessment Report, U.S. EPA, 1998).

10.4.2 Reductions in Emissions of Ozone Precursors

10.4.2.1 Description of Benefits and Overall Approach

This assessment of the benefits from reductions in emissions of ozone precursors due to the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule considers benefits derived from evaluating ozone air quality changes. The following sections present the results of the assessment of the benefits associated with reductions in VOC emissions and the adverse environmental impacts associated with increased emissions of sulfur dioxide (SO₂) and particulate matter (PM). Benefits are estimated using the methodology and data summarized in the November 5, 1997, OAQPS memo titled, “Benefits-Transfer Analysis for Pulp and Paper.” The methodology is based on the recently published benefits analysis provided in U.S. EPA, 1997, *Regulatory Impact Analyses for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule*. It is briefly discussed, and the results of the analyses are summarized. Details are available in the previously mentioned references, as well as in the Environmental Assessment Report.

Controlling VOC emissions is beneficial because some VOCs are precursors to ground-level ozone, which negatively affects human health and the environment. The technology selected for controlling VOC emissions (steam stripping) requires the consumption of energy. Increased energy consumption results in increased emissions of PM and SO₂. These byproducts of increased energy use can cause adverse environmental impacts. Therefore, EPA has assessed the benefits of reduced VOC emissions and impacts of increased PM and SO₂ emissions as described in the following sections. In effect, EPA subtracts the impacts of increased emissions of PM and SO₂ from the benefits associated with the control of VOCs.

10.4.2.2 Valuation of Benefits from Final Pharmaceutical Industry Effluent Guidelines

VOC Analysis

This assessment estimates that the Final Pharmaceutical Industry Effluent Guidelines will reduce VOC emissions from wastewater (at an estimated 50 facilities) in nonattainment areas alone by 1,254 Mg per year and in all areas by 3,608 Mg per year (see the Environmental Assessment Report). The estimate of the range of the value of a unit reduction in VOC emissions in 1990 dollars ranges from \$489 per Mg (does not

include mortality effects associated with ozone exposure) to \$2,212 per Mg (includes mortality effects).⁸

The estimated annual monetized benefits resulting from reductions in VOC emissions (not including adverse impacts of byproduct emissions of PM and SO₂) range from \$0.6 to \$8.0 million (\$1990). These results are summarized in Table 10-11.

PM Analysis

EPA estimates that the Final Pharmaceutical Industry Effluent Guidelines will result in an *increase* in PM emissions by 20 Mg per year (Environmental Assessment Report). The estimated value of a unit increase in PM emissions in 1990 dollars is \$10,823 per Mg.⁹ Therefore, EPA estimates that the annual monetized adverse environmental impacts resulting from increases in PM emissions due to this final rule are \$216,000 (\$1990).

SO₂ Analysis

EPA also estimates that the Final Pharmaceutical Industry Effluent Guidelines will result in an *increase* in SO₂ emissions of 52.1 Mg (51.8 Mg, eastern United States and 0.3 Mg, western United States) (Environmental Assessment Report). The estimate of the range of the value of a unit increase in SO₂ emissions in 1990 dollars is \$4,860 to \$10,763 per Mg of SO₂ for the eastern United States; and \$3,516 to \$4,194 per Mg of SO₂ for the western United States.¹⁰ Using these values, this assessment estimates that the annual monetized adverse environmental impacts resulting from increases in SO₂ emissions due to this final rule range from \$253,000 to \$559,000 per Mg (\$1990). These results are summarized in Table 10-12.

⁸ U.S. EPA, 1997. *Regulatory Impact Analyses for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule*.

⁹ *Ibid.*

¹⁰ *Ibid.*

Table 10-11

**Estimated Annual Human Health and Welfare Benefits from Reductions in VOC Emissions
Attributable to the Final Pharmaceutical Industry Effluent Guidelines (1990 dollars)**

	Excluding Ozone Mortality (nonattainment areas)	Including Ozone Mortality (all areas)
Dollar Value per Mg	\$489	\$2,212
VOC Emissions Reductions (Mg)	1,254	3,608
Monetized Benefits (excluding byproduct emissions)	\$613,000	\$7,980,000

Source: Environmental Assessment Report and U.S. EPA, 1997. *Regulatory Impact Analyses for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule.*

Table 10-12

Estimated Annual Adverse Environmental Impacts from Increases in SO₂ Emissions Attributable to the Final Pharmaceutical Industry Effluent Guidelines (1990 dollars)

	Eastern U.S.		Western U.S.		Total U.S.	
Type of Mortality	Short-term	Long-term	Short-term	Long-term	Short-term	Long-term
Dollar Value per Mg	\$4,860	\$10,763	\$3,516	\$4,194	---	---
SO2 Emissions Increases (Mg)	51.8	51.8	0.3	0.3	52.1	52.1
Adverse Monetized Impacts (due to increased emissions)	\$252,000	\$558,000	\$1,100	\$1,300	\$253,000	\$559,000

Source: Environmental Assessment Report and U.S. EPA, 1997. *Regulatory Impact Analyses for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule.*

Total Monetized Benefits

Total monetized air benefits attributable to the Final Pharmaceutical Industry Effluent Guidelines resulting from the reduction of ozone precursors (VOC emissions) from wastewater, after correction for PM and SO₂ increases, range from an adverse environmental impact of \$0.2 million (\$1990) to a benefit of \$7.5 million (\$1990). The breakout of these benefits is presented in Table 10-13.

10.4.2.3 Valuation of Benefits from MACT Standards Rule

VOC Analysis

Considering only the wastewater portion of sources covered by the MACT standards rule (at an estimated 23 facilities), EPA estimates that the MACT standards rule will result in reductions in VOC emissions in nonattainment areas alone and in all areas of 2,057 Mg to 16,619 Mg, respectively (Environmental Assessment Report). EPA estimates that the MACT standards rule also will produce benefits due to reductions in fugitive VOC emissions from process vents, storage tanks, and equipment leaks at an estimated 101 facilities in nonattainment and all areas (1,278 Mg and 4,027 Mg, respectively).¹¹ Considering the wastewater portion only and applying the estimate of the range of the value of a unit reduction of VOC emissions of \$489 per Mg to \$2,212 per Mg (\$1990),¹² EPA estimates that the annual monetized benefits resulting from reductions in VOC emissions (not including adverse impacts of byproduct emissions of PM and SO₂) range from \$1.0 million to \$36.8 million (\$1990). The annual monetized benefits from reductions in all four sources (not including adverse impacts of byproduct emissions) is \$1.6 million to \$45.7 million (\$1990). These results are summarized in Table 10-14.

¹¹ U.S. EPA, 1997. *Op. cit.*; EPA's Office of Water received pollutant removals for 101 facilities and costs for 98 facilities from OAQPS.

¹² *Ibid.*

Table 10-13

Total Monetized Benefits from Reductions in Ozone Precursors Attributable to the Final Pharmaceutical Industry Effluent Guidelines (1990 dollars)

Pollutant	Monetized Benefits	
	Low	High
VOC	\$613,000	7,980,000
PM	-\$216,000	-\$216,000
SO ₂	-\$559,000	-\$253,000
TOTAL	-\$162,000	7,510,000

Source: Environmental Assessment Report and U.S. EPA, 1997. *Regulatory Impact Analyses for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule.*

Table 10-14

Estimated Annual Human Health and Welfare Benefits from Reductions in VOC Emissions Attributable to the MACT Standards Rule (1990 dollars)

	Excluding Ozone Mortality (nonattainment areas)	Including Ozone Mortality (all areas)
Dollar Value per Mg	\$489	\$2,212
VOC Emission Reductions (Mg)		
- Wastewater	2,057	16,619
- Process Vents	936	2,949
- Storage Tanks	33	105
- Equipment Leaks	309	973
Monetized Benefits (excluding byproduct emissions)		
- Wastewater	\$1,010,000	\$36,800,000
- Process Vents	\$458,000	\$6,520,000
- Storage Tanks	\$16,100	\$232,000
- Equipment Leaks	\$151,000	\$2,150,000
TOTAL Monetized Benefits	\$1,640,000	\$45,700,000

Source: Environmental Assessment Report and U.S. EPA, 1997. *Regulatory Impact Analyses for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule.*

PM Analysis

EPA estimates that the MACT standards rule will result in an *increase* in PM emissions by 4.2 Mg per year (Environmental Assessment Report). Applying the estimated value of a unit increase in PM emissions of \$10,823 per Mg (\$1990),¹³ EPA estimates that the annual monetized adverse environmental impacts resulting from increases in PM emissions due to the MACT standards rule are \$45,500 (\$1990).

SO₂ Analysis

EPA estimates that the MACT standards rule will result in an *increase* in SO₂ emissions of 11.0 Mg (10.6 Mg, eastern United States, and 0.4 Mg, western United States) (Environmental Assessment Report). Applying the estimate of the ranges of the value of a unit increase in SO₂ emissions of \$4,860 to \$10,763 per Mg of SO₂ (\$1990) for the eastern United States and \$3,516 to \$4,194 per Mg of SO₂ (\$1990) for the western United States,¹⁴ EPA estimates that the annual monetized adverse environmental impacts resulting from increases in SO₂ emissions due to the MACT standards rule range from \$52,900 to \$116,000 (\$1990). These results are presented in Table 10-15.

Total Monetized Benefits

The total monetized air benefits attributable to the MACT standards rule resulting from reductions of ozone precursors (VOC emissions) from wastewater emission controls, after correction for PM and SO₂ increases, range from \$0.8 million (\$1990) to \$36.7 million (\$1990).

In addition, based on the OAQPS analysis of the 101 pharmaceutical manufacturing facilities covered by the MACT standards rule, EPA estimates that the reductions in fugitive VOC emissions from process vents, storage tanks, and equipment leaks would result in a range of monetized air benefits of

¹³ U.S. EPA, 1997. *Op. cit.*

¹⁴ *Ibid.*

Table 10-15

Estimated Annual Adverse Environmental Impacts from Increases in SO₂ Emissions Attributable to the MACT Standards Rule (1990 dollars)

	Eastern U.S.		Western U.S.		Total U.S.	
Type of Mortality	Short-term	Long-term	Short-term	Long-term	Short-term	Long-term
Dollar Value per Mg	\$4,860	\$10,763	\$3,516	\$4,194	---	---
SO2 Emissions Increases (Mg)	10.6	10.6	0.4	0.4	11.0	11.0
Adverse Monetized Impacts (due to increased emissions)	\$51,500	\$114,000	\$1,400	\$1,700	\$52,900	\$116,000

Source: Environmental Assessment Report and U.S. EPA, 1997. *Regulatory Impact Analyses for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule.*

\$0.6 million to \$8.9 million (\$1990).¹⁵ The total monetized benefits from reductions in VOC emissions from all four sources are estimated to be \$1.5 million to \$45.6 million (\$1990). The breakout of these benefits is presented in Table 10-16.

10.4.2.4 Potential Benefits Categories Not Quantified

In addition to acute health effects, ozone is believed to have chronic effects on the human respiratory system. The link between ozone concentration and such chronic health effects in humans, however, is not well understood. Therefore, this category of human health benefits is not considered quantitatively in this analysis. In addition, ozone-induced crop yield changes might have secondary effects due to the responses of the agricultural community to the yield change. For example, crops suffering from the effects of ozone are more susceptible to pestilence and result in an increased use of pesticides. Although the economic implications of these secondary effects of reduced crop yields might be significant, such impacts have not been quantified. Therefore, the resulting benefit estimates will understate the agricultural-related economic benefits of the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule.

10.4.3 Reductions in Cancer Risk

This section describes the assessment of cancer risk reductions expected to result from the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule due to reductions in VOC fugitive air emissions and reductions in pollutant loadings in wastewater discharged to surface waters. Details, including limitations, are available in the Environmental Assessment Report.

10.4.3.1 Reductions in Fugitive Air Emissions Attributable to the Final Pharmaceutical Industry Effluent Guidelines and MACT Standards Rule

Based on the cancer risk assessment for reductions in VOC emissions, EPA estimates that Final Pharmaceutical Industry Effluent Guidelines will result in the avoidance of 0.15 excess cancer cases per year nationwide due to reduced exposure to four identified carcinogens: benzene, chloroform, 1,2-dichloroethane,

¹⁵ U.S. EPA, 1997. *Op. cit.*

Table 10-16

**Total Monetized Benefits from Reductions in Ozone Precursors
Attributable to the MACT Standards Rule (1990 dollars)**

Pollutant	Monetized Benefits	
	Low	High
VOC	\$1,640,000	\$45,700,000
PM	–\$45,500	–\$45,500
SO ₂	–\$116,000	–\$52,900
TOTAL	\$1,480,000	\$45,600,000

Source: Environmental Assessment Report and U.S. EPA, 1997. *Regulatory Impact Analyses for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule.*

and methylene chloride (Environmental Assessment Report). EPA modeled 74 facility/pollutant release combinations and estimates that 17 facility/pollutant release combinations currently exhibit cancer risk levels exceeding 10^{-6} for a portion of the exposed population. EPA estimates that approximately 1 million people nationwide are exposed to these releases (based on 1990 population data).

The MACT standards rule will result in an additional estimated 0.88 cancer cases avoided per year nationwide via the inhalation exposure route (Environmental Assessment Report). This estimated decrease in cancer risk results from reductions in emissions of three carcinogens: chloroform, 1,2-dichloroethane, and methylene chloride. EPA modeled 43 facility/pollutant release combinations and estimates that 17 facility/pollutant release combinations currently exhibit cancer risk levels exceeding 10^{-6} for a portion of the exposed population. EPA estimates that approximately 4 million people nationwide are exposed to carcinogens as a result of these releases (based on 1990 population data). EPA also estimates that cancer risk will be further reduced due to reductions in fugitive air emissions from process vents, storage tanks, and equipment leaks. However, EPA did not quantify these reductions due to lack of site-specific data.

10.4.3.2 Reductions in Pollutant Loadings to Surface Waters Attributable to the Final Pharmaceutical Industry Effluent Guidelines and MACT Standards Rule

Based on the cancer risk assessment, the Final Pharmaceutical Industry Effluent Guidelines and MACT standards rule are estimated to result in much less than 0.0001 excess cancer cases avoided per year due to reductions in risk from exposure to contaminants in fish tissue and drinking water (Environmental Assessment Report). This estimate is small because the estimated baseline cancer incidence from consumption of fish tissue and drinking water potentially affected by discharges from pharmaceutical manufacturing facilities at current discharge levels is small.

EPA estimated the cancer risk from consumption of contaminated drinking water and fish tissue by evaluating the risks associated with the effluent from 17 direct dischargers and 113 indirect dischargers for 41 pollutants. EPA estimated the number of excess annual cancer cases avoided due to the final rule to be less than 0.0001 based on fish tissue ingestion. At current discharge levels, total cancer risk to subsistence anglers exceeds 10^{-6} due to the discharge of three carcinogens from three facilities into one stream. Given this risk level and the size of the population exposed, however, estimated cancer incidence is small. Thus, although the Final Pharmaceutical Industry Effluent Guidelines and MACT standards rule are expected to reduce the risk to acceptable levels (i.e., below 10^{-6}), the magnitude of the human health benefits is negligible.

Total cancer risk for recreational anglers and the general population is not expected to exceed 10^{-6} for any discharges. In the drinking water analysis, EPA estimated no excess annual cancer cases per year at baseline.

10.4.3.3 Valuation Methodology

A monetary value of benefits to society from avoided cancer cases is estimated if fugitive air emissions or wastewater discharges result in excess annual cancer cases with a magnitude significant enough to affect the analysis. The valuation of benefits is based on estimates of society's willingness-to-pay to avoid the risk of premature mortality. A review of willingness-to-pay studies recommends a range of \$1.6 to \$8.5 million (1986 dollars) for valuing an avoided event of premature mortality or a statistical life saved.¹⁶ Updating this 1986 value to 1990 dollars yields a range of \$1.9 to \$10.2 million. For this analysis of the Final Pharmaceutical Industry Effluent Guidelines, EPA uses the \$1.9 to \$10.2 million range for the value of life. A more recent survey of value of life studies by Viscusi also supports this range with the finding that value of life estimates are clustered in the range of \$3 to \$7 million (\$1990).¹⁷

10.4.3.4 Valuation of Benefits

Based on the cancer risk assessment conducted for fugitive air emissions, EPA estimates that the Final Pharmaceutical Industry Effluent Guidelines will result in 0.15 excess cancer cases avoided per year nationwide (Environmental Assessment Report). This result derives from reduced exposure to four identified carcinogens: benzene, chloroform, 1,2-dichloroethane, and methylene chloride. The estimated monetized value of the human health benefits from these cancer risk reductions ranges from \$285,000 to \$1.53 million (\$1990) annually. In addition, the MACT standards rule will result in 0.88 excess cancer cases avoided per year nationwide. This is due to reduced exposure to three identified carcinogens: chloroform, 1,2-dichloroethane, and methylene chloride. The estimated monetized value of the human health benefits from

¹⁶ Fisher, Ann, Lauraine G. Chestnut, and Daniel M. Violette, 1989. The Value of Reducing Risk of Death: A Note on New Evidence. *Journal of Policy Analysis and Management*. 8(1): 88-100.

¹⁷ Viscusi, W. Kip, 1992. *Fatal Tradeoffs: Public and Private Responsibilities for Risk*. New York: Oxford University Press.

Table 10-17

Estimated Annual Human Health Benefits from Cancer Risk Reductions (1990 dollars)

	Final Pharmaceutical Industry Effluent Guidelines		MACT Standards Rule	
	Low	High	Low	High
Number of Excess Cancer Cases Avoided	0.15	0.15	0.88	0.88
1990 Value of Life (millions of dollars)	\$1.9	\$10.2	\$1.9	\$10.2
TOTAL Monetized Benefits	\$285,000	\$1,530,000	\$1,670,000	\$8,980,000

Source: Environmental Assessment Report and Fisher, Ann, Lauraine G. Chestnut, and Daniel M. Violette. 1989. The Value of Reducing Risk of Death: A Note on New Evidence. *Journal of Policy Analysis and Management*. 8(1): 88-100.

these cancer risk reductions ranges from \$1.7 million to \$9.0 million (\$1990) annually. Results of these analyses are summarized in Table 10-17.

10.4.4 Environmental Benefits

The Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule are expected to generate environmental benefits by improving water quality. These improvements in water quality are expected to result from reduced loadings of toxic substances in the effluent of the regulated facilities. The environmental benefits expected to result from the final rules are discussed below.

10.4.4.1 Description of Benefits

A wide range of environmental benefits is associated with the maintenance and improvement of water quality. These benefits include use values (e.g., recreational fishing), ecological values (e.g., preservation of habitat), and passive use (intrinsic or nonuse) values (e.g., aesthetics). For example, water pollution might affect the quality of the fish and wildlife habitat provided by water resources, thus affecting the species using these resources. This, in turn, might affect the quality and value of recreational experiences of users, such as anglers fishing in the affected streams. EPA considers the value of the recreational fishing benefits and intrinsic benefits resulting from the Final Pharmaceutical Industry Effluent Guidelines and MACT standards rule, but does not evaluate the other types of ecological and environmental benefits (e.g., increased assimilative capacity of the receiving stream, protection of terrestrial wildlife and birds that consume aquatic organisms, and improvements to other recreational activities, such as swimming, boating, waterskiing, and wildlife observation) due to data limitations.

EPA evaluates the potential environmental benefits of the final regulations by estimating improvements in the recreational fishing habitats that are affected by pharmaceutical wastewater discharges. EPA first identifies stream segments for which the regulations are expected to eliminate all occurrences of pollutant concentrations in excess of both aquatic life and human health ambient water quality criteria (AWQC) or toxic effect levels (based on stream dilution modeling of 17 direct and 113 indirect dischargers of 41 pollutants to 102 streams). The elimination of pollutant concentrations in excess of AWQC is expected

to result in significant improvements in aquatic habitats. These improvements in aquatic habitats are then expected to improve the quality and value of recreational fishing opportunities. In addition, nonuse (intrinsic) benefits to the general public, as a result of the same improvements in water quality, as described above, are expected. These nonuse benefits (option values, aesthetics, existence values, and bequest values) are based on the premise that individuals who never visit or otherwise use a natural resource might nevertheless be affected by changes in its status or quality.

10.4.4.2 Valuation Methodology

The estimation of the monetary value to society of improved recreational fishing opportunities is based on the concept of a “contaminant-free fishery” as presented by Lyke.¹⁸ Research by Lyke shows that anglers might place a significantly higher value on a contaminant-free fishery than a fishery with some level of contamination. To estimate the increase in value resulting from elimination of pollutant concentrations in excess of AWQC, EPA multiplies the baseline value for benefiting stream segments by the incremental gain in value associated with achievement of the “contaminant-free” condition. Lyke’s estimate of the increase in value ranged from 11.1 percent to 31.3 percent. Multiplying by these values yields a range of expected increase in value for the pharmaceutical facility stream segments expected to benefit by elimination of pollutant concentrations in excess of AWQC.

Nonuse benefits are not associated with current use of the affected ecosystem or habitat, but arise rather from: (1) the *realization* of the improvement in the affected ecosystem or habitat resulting from reduced effluent discharges and (2) the value that individuals place on the *potential for use* sometime in the future. Nonuse benefits can be substantial for some resources and are conservatively estimated as one-half of the recreational benefits.¹⁹

¹⁸ Lyke, A, 1993. *Discrete Choice Models to Value Changes in Environmental Quality: A Great Lakes Case Study*. Thesis submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy (Agricultural Economics) at the University of Wisconsin-Madison.

¹⁹ Bergstrom, J.C., 1993. *Benefits and Cost Transfer in Natural Resource Planning*. Sixth Interim Report, Athens, GA: University of Georgia, Department of Agricultural and Applied Economics. Bergstrom reviewed a number of sources where use and nonuse values were estimated. Bergstrom estimates the relative magnitude of nonuse value to use value by estimating the ratio of the former to the latter. The 34 ratios estimated by Bergstrom range from 0.1 to 10 with a median ratio of 1.92. The assumption that nonuse values are half of use values therefore should result in conservatively low estimates of nonuse benefits.

10.4.4.3 Valuation of Benefits

To estimate some of the benefits from the improvements in water quality expected to result from the Final Pharmaceutical Industry Effluent Guidelines and MACT standards rule, EPA models instream concentration estimates and then compares these estimates to both aquatic life and human health AWQC or toxic effect levels. EPA estimates that modeled end-of-pipe pollutant loadings will decline by 71 percent, from 11.2 million pounds per year under current conditions to 3.3 million pounds per year under the final rules.²⁰ EPA, in the analysis comparing instream concentration levels to AWQC, estimates that current discharge loadings result in excursions of AWQC at five locations. The analysis also indicates that no excursions are expected to occur at these five sites under the final rules.

EPA estimates that the annual monetized recreational benefits to anglers associated with the expected changes in water quality range from \$0.4 million to \$1.5 million (\$1990) (Environmental Assessment Report). In addition, EPA estimates that the annual monetized intrinsic (nonuse) benefits to the general public, as a result of the same improvements in water quality, range from at least \$210,000 to \$748,000 (\$1990) (Environmental Assessment Report). These intrinsic benefits are estimated as half of the recreational benefits and may be significantly underestimated. Monetized benefits of \$232,000 to \$828,000 (\$1990) of the recreational benefits and \$116,000 to \$414,000 (\$1990) of the intrinsic benefits can be solely attributed to the Final Pharmaceutical Industry Effluent Guidelines. Benefits of both the Final Pharmaceutical Industry Effluent Guidelines and MACT standards rule are summarized in Table 10-18.

10.4.5 Effects at POTWs

The Final Pharmaceutical Industry Effluent Guidelines contain pretreatment standards for up to 26 pollutants (depending on subcategory) discharged to POTWs by pharmaceutical manufacturing facilities. EPA identified the pollutants to be addressed by pretreatment standards based on analyses of the quantity and concentration of pollutants in the wastewater discharged and the number of facilities that discharge the

²⁰ These loadings include several pollutants that are not being regulated. Considering only regulated pollutants, EPA expects loadings to decline by 78 percent, from 7.2 million pounds per year under current conditions to 1.6 million pounds per year under the Final Pharmaceutical Industry Effluent Guidelines and MACT standards rule.

Table 10-18

Estimated Environmental Benefits (1990 dollars)

	Final Pharmaceutical Industry Effluent Guidelines and MACT Standards Rule*	
	Low	High
Recreational Benefits	\$419,000	\$1,495,000
Intrinsic (Nonuse) Benefits	\$210,000	\$748,000
TOTAL Monetized Benefits	\$629,000	\$2,240,000

* Includes a portion of recreational and intrinsic monetized benefits (\$285,000 to \$1,000,000) that cannot be differentiated between Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule.

Source: Environmental Assessment Report.

pollutants. In addition, the MACT standards rule is expected to contribute to the improvement of conditions at POTWs, and these contributions are also discussed here. Although the benefits from reducing adverse effects at POTWs might be substantial, these benefits are not quantified due to data limitations.

10.4.5.1 Description of Benefits

EPA considers three potential sources of benefits to POTWs from the final pretreatment standards: (1) reductions in the likelihood of interference and passthrough; (2) reductions in health risks to POTW workers; and (3) reductions in costs potentially incurred by POTWs in analyzing toxic pollutants and determining whether, and the appropriate level at which, to set local limits. Each of these potential benefit categories is discussed below.

10.4.5.2 Reductions in Interference and Passthrough Problems

As part of the analysis of the effects of pretreatment standards, POTW influent levels are compared to available data on inhibition levels. In the analysis of the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule, EPA considers the potential impacts of effluent from 123 facilities discharging 34 pollutants to 94 POTWs. Under current conditions, inhibition problems are projected to occur at three POTWs for three pollutants: acetonitrile, diethylamine, and triethylamine. After the final rules, inhibition problems are projected to remain at the same three POTWs for one of the pollutants: acetonitrile.²¹ The benefits cannot be solely attributed to the Final Pharmaceutical Industry Effluent Guidelines. Although the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule are not expected to completely eliminate inhibition problems, the reduction in pollutant loadings is expected to reduce the severity of the impact. Sufficient data are not available to monetize these benefits.

²¹ These results include pollutants that will not be regulated. Considering only regulated pollutants, EPA projects that under current conditions, inhibition problems will occur at one POTW for two pollutants: diethylamine and triethylamine. After the Final Pharmaceutical Industry Effluent Guidelines and MACT standards rule are promulgated, EPA projects that no inhibition problems caused by regulated pollutants will occur.

Limited evidence is available on the extent to which discharges from pharmaceutical facilities cause POTWs to fail to comply with their permits. There are several documented incidents of large slug loads or accidental releases from pharmaceutical facilities that have negatively affected the environment, including fish kills, degradation of water quality, and odor problems.²² In addition, many pollutants currently are not controlled in POTW permits because information is lacking on the potential impacts of these pollutants on the environment. Although discharge and failure to treat unregulated pollutants technically do not constitute passthrough, these pollutants enter and potentially have negative effects on the environment.

10.4.5.3 Reductions in Health Risks to POTW Workers

Following procedures outlined in EPA's *Guidance to Protect POTW Workers from Toxic and Reactive Gases and Vapors*,²³ risks to POTW workers from exposure to toxics are evaluated under current conditions and under final pretreatment standards.²⁴ Occupational exposure levels at POTWs are modeled based on the mixture of vapors that can partition out of influent water into the surrounding air. Risks to POTW workers are evaluated comparing these estimated exposure levels to occupational Threshold Limit Values (TLVs). Toxic substances, particularly the VOCs, in effluent discharges to POTWs pose health risks to POTW workers. EPA evaluates effluent discharged by 131 pharmaceutical facilities to 89 POTWs. Applying the approach described above, EPA expects the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule to reduce occupational risk at 9 of the 14 POTWs where workers are potentially at risk due to exposure to primarily acetonitrile, benzene, chloroform, diethylamine, n-heptane, n-

²² Note that some of these releases might have been in violation of existing regulations, and thus it might be inappropriate to attribute benefits resulting from proper control of these releases to the final rule. However, if the final rule does reduce the likelihood of such releases, it might be argued that such benefits are attributable to the rule.

²³ U.S. EPA, 1992. *Guidance to Protect POTW Workers from Toxic and Reactive Gases and Vapors*. June. NTIS: PB92-173236/XAB. EPA/812/B-92/001.

²⁴ The analysis does not consider risks to sewer workers, assuming that these workers would not be exposed to toxic emissions for long periods of time without using protective gear.

hexane, methylene chloride, toluene, and triethylamine.²⁵ Reductions of occupational risk at five POTWs can be solely attributed to the Final Pharmaceutical Industry Effluent Guidelines. Data are not available to monetize this benefit.

10.4.5.4 Benefits from Reductions in Analytical Costs

Under the National Pretreatment Program, authorized POTWs are required to develop and implement programs to control pollutants discharged by facilities to their systems. Local limits are designed to prevent passthrough and interference, taking into account POTW-specific and effluent-specific characteristics, as well as to implement other specific components of the National Pretreatment Program. In setting local limits, POTWs might need to undertake analyses to determine which pollutants warrant local limits and at what numerical level. Conducting these analyses is expensive—in some cases, on the order of hundreds of thousands of dollars. Thus, establishing pretreatment standards benefits the POTWs by allowing them to avoid the costs of performing these analyses. In addition, it is more efficient to conduct such analyses at the national level, reducing the potential for duplication of effort. Furthermore, categorical pretreatment standards will bolster the legal authority of the local limits POTWs set. POTWs must comply with the requirements contained in effluent guidelines and standards as required in 40 CFR 403. Finally, the standards will allow POTWs to develop technically supportable local limits for nonregulated pollutants that are similar to the pollutants regulated under the pretreatment standards.

10.4.6 Reductions in Systemic Risk

The Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule are expected to generate human health benefits by reducing exposure to toxic substances that cause systemic (noncancer) effects, thus reducing the risks of these associated effects. As in the case of the cancer risk assessment, EPA evaluates systemic hazards from exposure to fugitive air emissions and consumption of contaminated fish tissue and drinking water. Based on this analysis, EPA expects reductions in fugitive air emissions from

²⁵ These results include impacts of acetonitrile, which will not be regulated. Considering only regulated pollutants, EPA expects the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule will reduce occupational risk at 11 of 13 POTWs where workers are potentially at risk.

wastewater due to the Final Pharmaceutical Industry Effluent Guidelines to result in reduced systemic hazard to 32,300 individuals due to reduced exposure to four identified toxic pollutants: ammonia, chlorobenzene, methyl cellosolve, and triethylamine. EPA estimates that reductions in fugitive air emissions from wastewater due to the MACT standards rule will result in reduced systemic hazard to 370,000 individuals due to reduced exposure to four identified toxic pollutants: ammonia, 4-methyl-2-pentanone, methyl cellosolve, and triethylamine. EPA also expects that reductions in fugitive air emissions from process vents, storage tanks, and equipment leaks will result in reduced systemic hazard. However, these benefits are not quantified due to data limitations. EPA expects that no systemic hazard reductions are expected to result from reduced exposure to contaminated fish tissue or drinking water based on the estimated hazard calculated for each receiving stream under either or both rules.

10.4.7 Other Unquantified Benefits

The above benefit analyses focus mainly on identified compounds with quantifiable toxic or carcinogenic effects. This approach leads to a potentially large underestimation of benefits, since some significant pollutant characterizations are not considered. For example, the analyses do not include the benefits associated with reducing the particulate load (measured as TSS), or the oxygen demand (measured as BOD and COD) of the effluents. TSS loads can degrade ecological habitat by reducing light penetration and primary productivity and through the accumulation of solid particles that alter benthic spawning grounds and feeding habitats. BOD and COD loads can deplete oxygen levels, which can produce mortality or other adverse effects in fish, as well as reduce biological diversity. The benefits analyses are further limited because they concentrate on projected excursions from established minimum standards and do not account for protection of higher quality conditions. Likewise, they do not account for prevention of future impacts that could occur due to increased effluent loadings.

10.4.8 Summary of Results

The estimated annual monetized benefits resulting from the Final Pharmaceutical Industry Effluent Guidelines and the wastewater emissions control portion of the MACT standards rule will range from \$0.7 million to \$11.3 million (\$1990). This range includes \$285,000 to \$1.0 million of the environmental benefits

that cannot be differentiated between the Final Pharmaceutical Industry Effluent Guidelines and the wastewater emissions control portion of the MACT standards rule. The annual monetized benefits resulting solely from the MACT standards rule are estimated to range from \$3.2 million to \$54.6 million (\$1990). Table 10-19 summarizes these benefits, by category. The range reflects the uncertainty in evaluating the effects of the final rules and in placing a dollar value on these effects. As previously discussed and as indicated in the table, these monetized benefits ranges do not reflect many of the benefit categories expected to result under the final rules, including reduced systemic human health hazards; improved POTW operations/conditions; and improved worker health at POTWs. Therefore, the reported benefit estimate understates the total benefits of the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule.

10.5 COST-BENEFIT COMPARISON

Table 10-20 presents the social costs and benefits of the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule. Only the costs and benefits of the selected effluent guidelines options are presented here.

As the table shows, the Final Pharmaceutical Industry Effluent Guidelines are associated with costs totaling \$49.6 million, with benefits totaling \$0.7 million to \$11.3 million (\$1990). With costs and benefits of the MACT standards rule included, costs of both rules are \$97.0 million (\$1990) and benefits of both rules range from \$3.9 million to \$65.9 million (\$1990). The largest benefit category is human health benefits, with about 90 percent of the total dollar value of benefits under the combined rules. Note that the estimate for benefits does not include the dollar value of many important benefits for which monetized estimates could not be developed. Examples of benefit categories not reflected in this estimate including reduced systemic human health hazards; improved POTW operations/conditions; and improved worker health at POTWs. Therefore, the reported benefit estimate understates the total benefits of the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule.

Table 10-19

**Potential Annual Economic Benefits from the Final Pharmaceutical Industry Effluent Guidelines and the MACT Standards Rule
(millions of 1990 dollars)**

Benefits Category	Estimated Economic Benefit			
	Pharmaceutical Industry Guidelines		MACT Rule	
	Low	High	Low	High
Reduced Emissions of Ozone Precursors	-\$0.162	\$7.51	\$1.48	\$45.6
Reduced Cancer Risk	\$0.285	\$1.53	\$1.67	\$8.98
Improved Environmental Conditions	\$0.629	\$2.24	Unquantified	Unquantified
Improved POTW Operations (Inhibition and Sludge Contamination), Occupational Conditions	Unquantified	Unquantified	Unquantified	Unquantified
Reduced Systemic Risk	Unquantified	Unknown	Unquantified	Unquantified
TOTAL Monetized Benefits	\$0.752	\$11.3	\$3.15	\$54.6

Note: The Final Pharmaceutical Industry Effluent Guidelines benefits include a portion of environmental monetized benefits that cannot be solely attributed to the effluent guidelines alone (\$285,000 to \$1 million, 1990 dollars). Specifically, two facilities included in the modeling were required to have MACT strippers and were also costed for additional strippers to meet the Final Pharmaceutical Industry Effluent Guidelines. Overall removals due to these strippers cannot be differentiated between the MACT standards rule and the Final Pharmaceutical Industry Effluent Guidelines requirements.

The benefit values attributable for the MACT standards rule associated with reduced ozone precursor emissions from the wastewater emissions control portion of the MACT standards rule include adverse impacts related to increased energy consumption. Adverse impacts due to increased energy consumption from control of the other sources are not quantified due to data limitations.

Table 10-20

Total Costs and Benefits of the Final Pharmaceutical Industry Effluent Guidelines and MACT Standards Rule
(thousands of 1990 dollars)

Type of Benefit	Total Social Cost or Benefit Effluent Guidelines	Total Social Cost or Benefit MACT Standards Rule	Total Social Cost or Benefit Effluent Guidelines + MACT Standards Rule
Compliance Costs	\$49,362	\$47,447	\$96,809
Administrative Costs	\$207	unquantified *	\$207
Unemployment Administrative Costs	\$11	\$10	\$21
Total Social Costs	\$49,580	\$47,457	\$97,037
Human Health Benefits **	\$123 - \$9,040	\$3,150 - \$54,600	\$3,273 - \$63,640
Recreational Benefits	\$419 - \$1,495	unquantified	\$419 - \$1,495
Nonuse Benefits	\$210 - \$748	unquantified	\$210 - \$748
POTW Benefits +	unquantified	unquantified	unquantified
Total Benefits ++	\$752 - \$11,300	\$3,150 - \$54,600	\$3,902 - \$65,900

* Administrative costs were not calculated for the MACT standards rule but are expected to be small relative to the total costs of the two rules combined.

** Includes ozone reductions and cancer reductions.

+ Data are not available to monetize this benefit.

++ This range includes \$285,000 to \$1.0 million (\$1990) (\$340,000 to \$1.2 million, \$1997) of the environmental benefits that cannot be differentiated between the Final Pharmaceutical Industry Effluent Guidelines and the wastewater emissions portion of the MACT standards rule. The total benefits numbers differ slightly from those presented in the preamble due to rounding of the benefits to two significant digits in the preamble.

Source: Table 10-6 and 10-19 of this EA.